

### **REMARKS**

This Amendment is submitted in response to the non-final Office Action mailed on March 11, 2005. Claims 1-48 are currently pending, of which claims 14 and 39 have been cancelled and claims 1, 2, 6, 8-10, 12, 13, 15-18, 20, 26, 42, and 43 have been amended. Claims 49-111 were previously cancelled. Claims 112-122 are new. Applicants respectfully submit that this application is in complete condition for allowance and request reconsideration of the application in this regard.

### **Rejections of Claims Under 35 U.S.C. § 112**

Claims 21-23, 34, 39, and 43 stand rejected as failing to comply with the enablement requirement. Dependent claim 39 has been cancelled. Applicants respectfully traverse the rejection of claims 21-23, 34, and 43.

Dependent claim 21 sets forth that "the flex circuit is configured to isolate flow of a cooling fluidic medium from a back surface of the RF electrode to a front surface of the RF electrode." The Examiner is referred to the Applicants' specification at page 14, lines 7-10. Dependent claim 22 sets forth that "the flex circuit is configured to create a reservoir for a cooling fluidic medium that gathers at a back surface of the RF electrode." The Examiner is referred to the Applicants' specification at page 14, lines 10-15. Dependent claim 23 sets forth that "the flex circuit includes trace components." The Examiner is referred to the Applicants' specification at page 17, lines 13-14. Dependent claim 34 sets forth "a tare button coupled with the force sensor." The Examiner is referred to the Applicants' specification at page 17, lines 3-12. Dependent claim 43 sets forth that "the outlet of the cooling fluidic medium channel has a

smaller cross-sectional area than a cross-sectional area of the inlet.” The Examiner is referred to the Applicants’ specification at page 13, lines 13-15.

Consistent with the examination guidelines set forth in MPEP Section 2164, Applicants submit that the information contained in the disclosure of the application is sufficient to permit those skilled in the relevant art to both make and use the claimed subject matter set forth in claims 21-23, 34, and 43. Therefore, Applicants respectfully request that this rejection be withdrawn.

#### **Rejections of Claims Under 35 U.S.C. § 102**

##### **Claims 1-7, 9, 11, 19, 42, and 48**

Claims 1-7, 9, 11, 19, 42, and 48 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,707,402 (Heim). The Examiner contends that *Heim* shows or teaches all the elements of the rejected claims. Applicants respectfully traverse the rejection for the reasons set forth below.

In contrast to as-amended independent claim 1, *Heim* does not disclose or suggest an electrode assembly with “a least one RF electrode with a dielectric portion configured to contact the tissue and a conductive portion disposed on the dielectric portion” with “the dielectric portion and the conductive portion being arranged such that RF energy is capacitively coupled from the conductive portion for delivery into the tissue by transmission through the dielectric portion.” In contrast, *Heim* discloses an electrode (106) that transfers an electric current (EC) to a tissue region (TR). The transferred electric current heats the tissue region sufficient to provide a surgical effect that cuts the tissue. *Heim* does not disclose that the electrode (106) includes a dielectric portion configured to contact the tissue and a conductive portion disposed on the

dielectric portion. In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Moreover, *Heim* does not provide any suggestion to modify the electrode (106) to include dielectric and conductive portions. Therefore, for at least this reason, Applicants respectfully request that the rejection be withdrawn.

In further contrast to independent claim 1, *Heim* does not disclose or suggest “a handpiece assembly including a handpiece housing and a cooling fluidic medium valve member.” Instead, *Heim* discloses a valve (34) that controls liquid flow in conduit (60) connecting a liquid supply (30) with the surgical pencil (10) and another valve (46) that controls gas flow in conduit (70) connecting a gas supply (40) with the surgical pencil (10). Neither of these valves (34, 46) forms an assembly with the surgical pencil (10). Moreover, *Heim* does not provide any motivation or suggestion for relocating the valves (34, 46) to form an assembly with the surgical pencil (10). Therefore, for at least this additional reason, Applicants respectfully request that the rejection be withdrawn.

Because claims 2-7, 9, 11, 19, 42, and 48 depend from independent claim 1, Applicants submit that these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Heim*

**Rejection of Claims under § 103(a)****Claims 8, 10, 14-18, and 40-41**

Claims 8, 10, 14-18, and 40-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Heim* in view of U.S. Patent No. 5,755,753 (*Knowlton*). Because claims 8, 10, 15-18, and 40-41 depend from independent claim 1, which has been amended to include the subject matter of dependent claim 14, now cancelled, Applicants submit that these claims are also patentable for at least the same reasons discussed above. Furthermore, each of these claims recites a unique combination of elements not disclosed or suggested by the combination of *Heim* with *Knowlton*.

Applicants further submit that the Examiner's motivation to combine these references is improper. The Office Action states that the "motivation would be to use a well-known design expedient (as evidenced by its presence in the prior art)." According to MPEP § 2143.01, "a statement that modifications of the prior art to meet the claimed invention would have been well within the ordinary skill of the art at the time the claimed invention was made because the references relied upon teach that all aspects of the claimed invention were individually known in the art is **not** sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references." Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (emphasis added); *see also In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000). Hence, the conclusory rationale offered in the Office Action fails to provide an objective reason to combine the teachings of *Heim* with *Knowlton*. In fact, the Examiner's reliance upon common knowledge in the art or "well known" prior art is misplaced and violates the examination guidelines set forth in MPEP § 2144.03. The Examiner's reliance is misplaced because, even assuming *arguendo* that

the subject matter of each dependent claim is conventional, the Examiner fails to address whether it would have been obvious to modify the surgical pencil (10) shown in *Heim* to include the structures allegedly disclosed in *Knowlton*.

For example, independent claim 1 now recites that the RF electrode includes a tissue-contacting dielectric portion and a conductive portion disposed on the dielectric portion. Constructing the RF electrode with a tissue-contacting dielectric portion through which RF energy is transmitted from the conductive portion and into the tissue has various advantages, as explained in Applicants' specification at page 12, lines 17-26:

Dielectric portion 30 creates an increased impedance to the flow of electrical current through RF electrode 20. This increased impedance causes current to travel a path straight down through conductive portion 28 to the skin surface. Electric field edge effects, caused by a concentration of current flowing out of the edges of RF electrode 20, are reduced.

Dielectric portion 30 produces a more uniform impedance through RF electrode 20 and causes a more uniform current to flow through conductive portion 28. The resulting effect minimizes or even eliminates, edge effects around the edges of RF electrode 20.

As explained above, *Heim* fails to disclose an RF electrode having a tissue-contacting dielectric portion and a conductive portion disposed on the dielectric portion. Moreover, *Heim* fails to suggest any advantage to be gained by modifying the RF electrode (106) to include a tissue-contacting dielectric portion through which RF energy is transmitted from a metal portion by capacitive coupling into the tissue. Instead, *Heim* conductively couples energy from the electrode (106) directly to the tissue. As a result, energy leaves the electrode (106) about the electrode edges, which results in very high current densities at the edges and no current density in the electrode interior. In contrast, capacitively coupling energy through a dielectric portion of an electrode delivers energy to the tissue without burning. Capacitively coupled

energy is distributed across the entire electrode area. As a result, more energy may be delivered with lower density at any given point. The higher energy delivery with low density results in true "volumetric" heating, which creates more uniform heating and improved tissue contraction. Heating at the electrode edges alone delivers insufficient energy to elevate the temperature of bulk tissue high enough to obtain a therapeutic result.

A metal electrode capacitively and conductively couples energy to tissue. If the metal electrode does not touch the skin, the capacitive coupling component will increase. However, the amount of capacitance will vary too much because of, among other factors, an inability to maintain a constant spacing and, hence, will not be predictable or controllable with enough certainty. On the other hand, an electrode with a metal portion that capacitively couples energy through a tissue-contacting dielectric portion to the tissue, as set forth in Applicants' claim 1, defines a capacitor structure in which all capacitance variables can be engineered into the design. The capacitor structure results in a highly predictable energy distribution that allows maximum energy to be delivered with minimal risk of burning at any given point. As described at various locations in the *Heim* specification, the electrode (106) cuts the tissue, which is an extreme form of tissue burning, and may even pyrolyze the tissue, which is an even more extreme form of tissue burning.

The Examiner contends at page 6, paragraph 2 of the Office Action that *Knowlton* discloses an "RF electrode (26) [that] includes a conductive portion (obvious to 'electrode') and a dielectric (18) portion (col. 4:57-64)." Reference numeral (18) in *Knowlton* refers to a porous membrane (18). There is no motivation found in either *Knowlton* or *Heim* to modify the surgical pencil (10) disclosed in *Heim* to include a porous membrane (18) that contacts the tissue and "is adapted to receive an electrolytic solution (20)" and "becomes inflated to substantially conform

to a contacting exterior surface 22 of porous membrane (18) which is in close thermal contact with epidermis (12).” See *Knowlton* at column 4, lines 50-56. The device disclosed in *Knowlton* is not intended to cut the tissue, as is the electrode (106) disclosed in *Heim*. Instead, the device disclosed in *Knowlton* is intended to deliver energy without damage or surgical intervention. See *Knowlton* at column 2, lines 32-36. Attempting to modify the electrode (106) in *Heim* with the porous membrane (18) of *Knowlton* would change the principle of operation of the electrode (106) in *Heim*. In fact, *Heim* discloses at column 2, lines 38-44 that excess liquid may interfere with achieving the desired surgical effect.

Therefore, for at least these additional reasons, Applicants respectfully request that this rejection be withdrawn.

Claims 38, 44, and 45

Claims 38, 44, and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Heim* in view of U.S. Patent No. 5,234,428 (Kaufman). Because claims 38, 44, and 45 depend from independent claim 1, Applicants submit that these claims are also patentable for at least the same reasons discussed above. Furthermore, each of these claims recites a unique combination of elements not disclosed or suggested by the combination of *Heim* with *Kaufman*. Applicants further incorporate by reference the discussion above regarding the Examiner’s improper motivation (i.e., “to use a well-known design expedient (as evidenced by its presence in the prior art)”) to combine these references in the manner suggested. For at least this additional reason, Applicants respectfully request that this rejection be withdrawn.

Claim 13

Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Heim* in view of U.S. Patent No. 5,041,110 (Fleenor). Because claim 13 depends from independent claim 1, Applicants submit that this claim is also patentable for at least the same reasons discussed above. Furthermore, this claim recites a unique combination of elements not disclosed or suggested by the combination of *Heim* with *Fleenor*. Applicants further incorporate by reference the discussion above regarding the Examiner's improper motivation (i.e., "to use a well-known design expedient (as evidenced by its presence in the prior art)") to combine these references in the manner suggested. For at least this additional reason, Applicants respectfully request that this rejection be withdrawn.

Claims 20, 24, and 26-33

Claims 20, 24, and 26-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Heim* in view of U.S. Patent No. 5,396,887 (Imran). Because claims 20, 24, and 26-33 depend from independent claim 1, Applicants submit that these claims are also patentable for at least the same reasons discussed above. Furthermore, each of these claims recites a unique combination of elements not disclosed or suggested by the combination of *Heim* with *Imran*. Applicants further incorporate by reference the discussion above regarding the Examiner's improper motivation (i.e., "to use a well-known design expedient (as evidenced by its presence in the prior art)") to combine these references in the manner suggested. For at least this additional reason, Applicants respectfully request that this rejection be withdrawn.

With specific regard to dependent claim 20, The Examiner contends that *Imran* discloses a "flex circuit (51; Figure 2)". However, there is no motivation found in either *Imran*



or *Heim* to modify the surgical pencil (10) disclosed in *Heim* to include a flex circuit (51) as disclosed by *Imran*. The flex circuit (51) in *Imran* is part of an electrical assembly (47) for a pressure transducer (27), which measures contact pressure against a heart wall to avoid damaging or puncturing the heart wall. See *Imran* at column 3, line 51 – column 4, line 12. *Heim* does suffer from this problem and would not require pressure monitoring as the intent is to puncture and damage the tissue using the electrode (106) so as to cut tissue. Consequently, there is no motivation to combine *Imran* with *Heim*, as suggested by the Examiner. For at least this additional reason, Applicants respectfully request that this rejection be withdrawn.

#### Claims 35-37

Claims 35-37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Heim* in view of U.S. Patent No. 4,655,215 (Pike). Because claims 35-37 depend from independent claim 1, Applicants submit that these claims are also patentable for at least the same reasons discussed above. Furthermore, each of these claims recites a unique combination of elements not disclosed or suggested by the combination of *Heim* with *Pike*. Applicants further incorporate by reference the discussion above regarding the Examiner's improper motivation (i.e., "to use a well-known design expedient (as evidenced by its presence in the prior art)") to combine these references in the manner suggested. For at least this additional reason, Applicants respectfully request that this rejection be withdrawn.

#### Claims 46 and 47

Claims 46 and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Heim* in view of U.S. Patent No. 5,395,363 (Billings et al.). Because claims 46 and 47 depend

from independent claim 1, Applicants submit that these claims are also patentable for at least the same reasons discussed above. Furthermore, each of these claims recites a unique combination of elements not disclosed or suggested by the combination of *Heim* with *Billings et al.*

Applicants further incorporate by reference the discussion above regarding the Examiner's improper motivation (i.e., "to use a well-known design expedient (as evidenced by its presence in the prior art)") to combine these references in the manner suggested. For at least this additional reason, Applicants respectfully request that this rejection be withdrawn.

#### New Claims

Claims 112 and 113, which are new, depends from independent claim 1 and are patentable for at least the same reasons as claim 1. Furthermore, each of these claims recites a unique combination of elements not disclosed or suggested by the references of record.

Claim 114 is a new independent claim and sets forth that the electrode assembly includes "a flex circuit including a dielectric layer and a conductive RF electrode layer disposed on the dielectric layer, the flex circuit being thin and flexible." As Applicants remarked above, there is no motivation found in either *Imran* or *Heim* to modify the surgical pencil (10) disclosed in *Heim* to include a flex circuit (51) as disclosed by *Imran*. For at least the same reason, claim 114 is patentable over the combination of *Imran* with *Heim*.

Because claims 115-122 each depend from independent claim 114, Applicant submits these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by the art of record.

**Conclusion**

Applicants have made a bona fide effort to respond to each and every requirement set forth in the Office Action. In view of the foregoing amendments and remarks, this application is submitted to be in complete condition for allowance and, accordingly, a timely notice of allowance to this effect is earnestly solicited. If there is any additional matter that may be resolved by telephone or fax, the Examiner is invited to contact the undersigned to expedite issuance of this application.

Applicants do not believe that any fees are due in connection with this submission, other than a three-month extension fee under 37 CFR 1.136. However, if such petition is due or any additional fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to deposit account 23-3000.

Respectfully submitted,

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